

HMS DCE Disclosure and Content Attestation – Course Directors/Planners

*****Please Complete and Return to Course Director*****

CME activities are intended to serve the public interest. To this end it is the policy of the Harvard Medical School Department of Continuing Education (HMS DCE) that all its educational activities be balanced, scientifically rigorous, objective, and independent of commercial influence. The purpose of this form is to help us identify and resolve all conflicts of interests that arise from financial relationships with commercial entities producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients¹. The ACCME requires that providers identify “relevant financial relationships”—defined as financial relationships in any amount occurring within the past 12 months that create a conflict of interest—of the individual involved in CME and his or her spouse or partner.

What is a “conflict of interest”? (ACCME Standard for Commercial Support - Standard 2.1 [SCS 2.1])

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

Where is the “conflict?” (SCS 2.1)

When the provider’s interests are aligned with those of a commercial interest the interests of the provider are in “conflict” with the interests of the public. The interests of the people controlling CME must always be aligned with what is in the best interests of the public.

How do these circumstances create a conflict of interest? (SCS 2.1)

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias. Commercial bias is prohibited in CME.

When a conflict of interest exists, it must be resolved prior to participation in the CME activity. Thus, the first step in this process is identifying such conflicts so that they may then be resolved through Harvard’s process of conflict of interest resolution.

The ACCME mandates that individuals who refuse to disclose will be disqualified from serving in any of the following capacities: course director, planner, faculty, or a reviewer and will not have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

For academic planners this form will be reviewed by a non-conflicted course director, non-conflicted physician proxy (if the course director is conflicted) or an HMS DCE staff member. If a conflict of interest exists, a remedy will be determined by the course director, following HMS DCE’s policy on resolving conflicts of interest.

For course directors this form will be reviewed by a non-conflicted CME Reviewer, a non-conflicted member of the HMS CME Committee, or an HMS DCE staff member. If a conflict of interest exists, the Activity Proposal will receive a medical review by a non-conflicted physician selected by HMS DCE.

HMS DCE and/or the course directors will disclose relevant financial relationships to activity participants.

Complete form on next page...

¹ For the purposes of this form do not consider providers of clinical service directly to patients to be a “commercial entity.”

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Activity Title:		Activity Date and Activity Number:	
Name:			
Role(s) in Activity	<input type="checkbox"/> Course Director	<input type="checkbox"/> Academic Planner*	<input type="checkbox"/> Faculty <input type="checkbox"/> Reviewer
If Faculty: Content: (e.g., title of presentation(s) or session, topic(s), etc.)			

On Behalf of Yourself and Your Spouse/Partner

In regard to financial relationships with commercial entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients relevant to the content I am planning, developing, presenting, or evaluating

Check One of The Boxes Below (Pertaining to the Last 12 Months):

<input type="checkbox"/> We have no financial relationships with such commercial entities.			
<input type="checkbox"/> We disclose the following financial relationships with such commercial entities:			
Recipient: Self or Spouse/Partner	Company	Type of Relationship**	Content Area (if applicable)

(Attach an additional sheet if you need more room)

To Be Completed by Non-Conflicted Reviewer <u>Based on the Relationships Disclosed Above</u>			
Relevant relationships exist – COI action required	<input type="checkbox"/> Disclosure has been reviewed and at least one relevant relationship exists. Based on this, the conflict of interest(s) must be resolved. Complete and submit the Resolution of Conflict of Interest Form. Disclosure to participants should state the individual’s name, degree(s), the company’s name and the type of relationship with the company.		
No relevant relationships exist	<input type="checkbox"/> Disclosure has been reviewed and no relevant relationships exist. Based on this, no conflict of interest resolution needed. Disclosure to participants should state the individual’s name, degree(s) and “No relevant financial relationships to disclose”		
Reviewer’s Name		Date of Review	
Reviewer’s Role	<input type="checkbox"/> DCE Staff Member <input type="checkbox"/> DCE Selected Medical Peer-Reviewer <input type="checkbox"/> Non-conflicted Course Director <input type="checkbox"/> Non-conflicted Physician Appointed by the Course Director		

* Academic Planners include any individual who has influenced the content of the activity. This may include Course Administrators and the HMS CME Committee as well as other individuals.

** **Type of relationship may include:** full-time or part-time employee, management position, independent contractor, consultant, research or other grant recipient, paid speaker or teacher, membership on boards, advisory committees, or review panels, ownership interest (product royalty/licensing fees, owning stocks, shares, etc), or any other financial relationship.

ATTESTATIONS

Please indicate your understanding of and willingness to comply with each statement below. They are based on requirements of the ACCME and the AMA. If you have any questions regarding your ability to comply, please contact the course director as soon as possible. (A=Agree, D=Disagree, N/A = Not Applicable)

A	D	
<input type="checkbox"/>	<input type="checkbox"/>	On this form I have disclosed all relevant financial relationships, and I will disclose this information to learners verbally (for live activities) and in print. If I have no financial relationships I will disclose this to the learners. I will make such disclosure prior to the beginning of the activity.
<input type="checkbox"/>	<input type="checkbox"/>	The content and/or presentation of the information with which I am involved will promote quality or improvements in healthcare and will not promote a specific proprietary business interest of a commercial entity. I understand that if I am presenting at a live event, a CME monitor may be attending to ensure that my presentation is educational, and not promotional, in nature.
<input type="checkbox"/>	<input type="checkbox"/>	I have not and will not accept any honoraria, additional payments or reimbursements for this CME activity from a commercial entity.
<input type="checkbox"/>	<input type="checkbox"/>	I will not plan social events or meals that compete with or take precedence over the educational events.
<input type="checkbox"/>	<input type="checkbox"/>	I will ensure that any commercial support associated with this activity has been given with the full knowledge and approval of the HMS Department of Continuing Education.
<input type="checkbox"/>	<input type="checkbox"/>	If this activity will have commercial exhibits or advertising, I will ensure that arrangements for exhibits or advertising will not influence planning or interfere with the presentation, nor will they be a condition of the provision of commercial support for this activity. I will also ensure that exhibits and advertising are not in the same room as the educational activity.
<input type="checkbox"/>	<input type="checkbox"/>	I understand HMS Department of Continuing Education's financial policies and will abide by them.
<input type="checkbox"/>	<input type="checkbox"/>	I am now and have been in compliance with legal requirements and ACCME policies pertaining to my activities as a course director, academic planner, faculty member and/or reviewer.

A	D	N/A	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Content Validation and Commercial Bias <ol style="list-style-type: none"> 1) All the recommendations involving clinical medicine related to my content will be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. 2) All scientific research referred to, reported or used in my content in support or justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection and analysis. To help learners judge the quality of data provided, I will present the source and type or level of evidence (i.e. animal study, randomized controlled trial, meta-analysis, etc.). 3) Research findings and therapeutic recommendations in my content will be based on scientifically accurate, up-to-date information and be presented in a balanced, objective manner.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I make use of the material of others and such use does not or may not reasonably fall within the fair use doctrine of the United States copyright law, I will obtain the appropriate written permissions and provide appropriate attribution.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For any drug/product discussed, the data must be objectively selected and presented, both favorable and unfavorable information about the drug/product must be fairly presented, and I will include information about reasonable alternative treatment options. Where there is a suggestion of superiority of one drug/product over another, this suggestion needs to be supported by evidence-based data.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am discussing specific healthcare products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any single company.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am discussing any drug/product use that is unlabeled or investigational, I will disclose that the use or indication in question is not currently approved by the FDA.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I have been trained or engaged by a commercial entity or its agent as a speaker (e.g. speaker's bureau) for any commercial interest, the promotional aspects of that presentation will not be included in any way with this activity.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	I understand that a non-conflicted medical reviewer may need to review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance as requested.

I have carefully read and considered each item in this form, and have completed it to the best of my ability.

Printed Name

Signature

Date